

DEPARTMENT OF VETERANS AFFAIRS
VA San Diego Healthcare System
Mail Code 151
3350 La Jolla Village Dr.
San Diego, CA 92161

Human Research Protection Program
Institutional Review Board

Date: January 14, 2019
From: VA San Diego Healthcare System IRB
Re: IRB Protocol Number: H120108
Title: Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis
Nickname: InTeam
Submission Reference Number: 031826
To: (b) (6) [REDACTED]

The IRB Protocol Amendment submitted on 12/03/2018 for the above-referenced protocol was reviewed on 01/10/2019 by the VA San Diego Healthcare System Institutional Review Board (IRB).

The Committee disapproved the request to amend the study based on the following:

This study has been on hold since May 2018, upon initiation of an IRB investigation into research-related allegations. In October 2018, the IRB determined that serious noncompliance had occurred. As part of the remediation, the IRB required that the PI amend the protocol to accurately describe how research specimens would be obtained should this protocol be released for reactivation. The IRB understands that the PI consulted with Pathology and Interventional Radiology and submitted the amendment as requested by the IRB. However, the IRB also understands that enrollment is now closed at all participating sites and all sites are working with the master-site to appropriately closeout the study.

Therefore, the IRB acknowledges that the local PI complied with the IRB's required remediation plan, but disapproved the request to amend the study because the study will be closed. This study will remain on hold until any remaining remediation is completed and the IRB reviews and approves a closure application.

On behalf of the Institutional Review Board,
(b) (6) [REDACTED]

VASDHS IRB Chair

cc R&D Committee